Amendments to the Claims

No amendments to the claims have been made.

Listing of Claims

Claims 1,2 and 5-20 are pending in the application

REMARKS/ARGUMENTS

The Applicant requests the Final Rejection be withdrawn since the rejection is based on new grounds, particularly GB patents as referenced by the Examiner found on Applicant's page 14 of the Specification. Also, Applicant respectfully disagrees with the Examiner's reasons for rejecting claims 1,2 and 5-20 under 35 U.S.C. 103 over EP 0 224 352 and GB patents found on page 14 of applicant's Specification, since the jet or stream limitations claimed in the instant case reduce unwanted systemic absorption of the ophthalmic solution, while increasing the exposure of the ophthalmic target to an ophthalmic solution.

Examiner Final Rejection Should be Withdrawn

Although the Examiner makes the instant rejection based on the Applicant's alleged disclosure, such a rejection was not cited in the Examiner's previous Action. This Final Rejection is not based on Applicant's previous amendment to the claims, nor is this Final Rejection based on art cited by the Applicant in an IDS. Therefore, this Final Rejection should be withdrawn since the Examiner introduced a new ground of rejection that was neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement. See MPEP § 706.07(a).

Prima Facie Case of Obviousness not Met by Examiner

As stated in the previous response, EP 0 224 352 does not envision an embodiment where the method of discharge is anything other than electrically charged ophthalmic spray. Examiner contends EP 0 224 352 teaches Applicants' invention, but for the droplet diameter and discharge velocity, which one of reasonable skill in the art could determine with respect to claim 1. Specifically, EP 0 224 352 teaches an ocular drug delivery device and process for generating a spray for ocular treatment, which is achieved by raising the ophthalmic solution to a high potential within the spray nozzle of the device thereby causing the

formulation to atomize as a spray of electronically charged droplets. EP 0 224 352 does not disclose a dosage form that is a moving volume of liquid droplets having a length and diameter that remain substantially the same after exiting the delivery device. EP 0 224 352 instead discloses a spray, i.e. atomized liquid, that increase in diameter and length after exiting a delivery device, without suggesting alternative delivery forms such as jet or stream. A spray is not equivalent to the Applicant's claimed jet or stream of solution, since sprays not only lack the momentum required by the instant claims to deliver horizontally, but sprays also disperse over a wider distance. As the spray discharges over a wider area, the spray poses an increased risk of exposure to the skin surrounding the eye. In the case where the ophthalmic solution is a prostaglandin for example, See Applicant's Speciation page 12 line 23, this exposure potentially leads to changes in eyebrow color, skin discoloration, or other periocular side effects, since it is well known in the art that prostaglandin exposure to these areas causes the aforementioned conditions. A jet or stream assures that the ophthalmic solution is received into the eye rather than onto an area of the body that may become malaffected by the ophthalmic solution used. Additionally, a jet or stream can be directed or targeted at a chosen site in an eye, e.g. cornea, anterior bulbar conjunctiva, posterior bulbar conjunctiva, or palpebral conjunctiva where the active compound can be most readily absorbed. Since EP 0 224 352 use of a spray teaches away from the Applicants' claimed invention, the 35 U.S.C. 103 rejection based on this art should therefore be withdrawn.

As to the GB references found on page 14 of the Applicant's specification as referenced by the Examiner which allegedly references a jet or stream, this art may not be used as prior art under 35 U.S.C. 103 since the instant application has a priority date of December 21, 1995, thereby resulting in a filing date prior to publication of both GB cited references. Since neither GB reference may be used to substantiate a 35 U.S.C. 103 rejection, it follows the Examiner has not met the prima facie burden of obviousness and it is respectfully requested that all rejections be withdrawn.

Applicants respectfully request that a timely Notice of Allowance be issued in this case.

A one month extension of fee is included herewith the present submission. If any additional fee is required for the filing of this response, including extensions of time for which Applicants hereby petition, please charge all such required fees to Deposit Account No. 500329.

Respectfully submitted,

Date: 4/14/05

Angela J. Grayson
Attorney For Applicants
Registration No. 54,136

Agouron Pharmaceuticals, Inc./A Pfizer Company
Patent Department
10777 Science Center Drive
San Diego, California 92121
Phone: (858) 622-8872
Fax: (858) 678-8233